

REMARKS

35 U.S.C. § 112 ¶ 1 Claim Rejections

The Examiner has rejected claims 40-50 and 73-74 as failing to comply with the written description requirement under 35 U.S.C. § 112 ¶ 1 because the Examiner argues that the specification does not provide support for the term “non-mesh” structure. In response, Applicant has amended claim 40 to remove the term “non-mesh” structure. Thus, the Examiner’s rejection is obviated since none of the pending claims use the terminology objected to by the Examiner, including the new claims that Applicant has added to the application. Therefore, the Examiner may now withdraw § 112 ¶ 1 rejections.

Drawing Objections

The Examiner has objected to the drawings because the Examiner argues that “a non-mesh stent formed of more than one frame thread, and the thread comprising a full circle must be shown or the feature(s) canceled from the claims(s).” As explained above, the term “non-mesh” has been removed from the claims. Thus, this objection has been obviated. In addition, the Examiner appears to have misunderstood the claim language that refers to “a full circle.” It is not the frame thread itself that comprises a full circle; it is the complete support frame that forms the full circle around the circumference of the support frame. Claim 40 has been amended in order to clarify this distinction. Therefore, the Examiner may now withdraw the objections to the drawings.

35 U.S.C. § 112 ¶ 2 Claim Rejections

The Examiner has rejected claims 40-50 and 73-74 as being indefinite under 35 U.S.C. § 112 ¶ 2 because the Examiner argues that the term “thereabout” is unclear. In response, Applicant has amended claim 40 to remove the term “thereabout.” Thus, the Examiner’s rejection is obviated since none of the pending claims use the terminology objected to by the Examiner, including the new claims that Applicant has added to the application. Therefore, the Examiner may now withdraw § 112 ¶ 2 rejections.

35 U.S.C. § 103 Claim Rejections

The Examiner has rejected claims 40-48, 50 and 73-74 as being unpatentable under 35 U.S.C. § 103(a) over Summers (U.S. Patent No. 6,080,191) in view of Davila et al. (U.S. Patent No. 6,245,100) in further view of McCrory (U.S. Patent No. 5,951,599). The Examiner has also rejected claim 49 as being unpatentable under 35 U.S.C. § 103(a) over Summers in view of Davila and McCrory in further view of Wulfman et al. (U.S. Patent Publication No. 2003/0139802).

Applicant has carefully considered the Examiner's comments. In response, Applicant has amended claims 40 and 49-50 and has added claims 75-91. Claim 48 has been cancelled. Applicant respectfully submits that the claims as now presented are allowable over the prior art of record.

In particular, claims 40, 78 and 84 recite that the graft material is "laying on an outer surface" of the support frame and the graft material "thereby covering the portion of the support frame contacting the graft material." This limitation is described in Applicant's specification in paragraph [0036]. Specifically, the specification describes two alternative ways of securing graft materials to support frames. First, a graft material may be "formed over a portion of the frame 12, effectively embedding the frame 12 in the graft material 14." Second, "the graft material 14 can be secured to the support frame 12 by suitable attachment means Preferably, the graft material 14 in this arrangement simply lies on the support frame 12, covering the portion of the frame 12 that contacts the graft." Accordingly, claims 40, 78 and 84 are directed to the second alternative described where the graft material is not embedded on the support frame, but instead, lies loosely on the support frame and is secured to the support frame with separate attachment means, such as sutures or adhesive connecting two layers of the graft material. This limitation is not disclosed by the prior art relied upon by the Examiner. In particular, the Examiner relies upon Davila, which the Examiner argues "teaches that it [is] advantageous to fix a graft to a stent by folding the ends over the stent frame and attaching the layers to one another." However, the graft material in Davila is "bonded to the outer stent 60, preferably by the application of heat and pressure." (Col. 9, lines 6-8). This is precisely the type of prior art that is distinguished

in Applicant's specification as noted above. As presently amended, Applicant's claims 40, 78 and 84 do not cover stent-grafts, such as Davila, where the graft material is embedded onto the support structure. Thus, Davila fails to disclose the limitations of Applicant's claims as now presented. Moreover, as now amended, claims 40, 78 and 84 recite that the graft material "cover[s]" the support structure and is secured to the support structure by "folding" the ends of the graft material around the one or more frame threads "and along an inner surface of the support frame." As shown in Figure 1 of Applicant's specification, the graft material lies on the outer surface of the stent, and the end of the graft material is folded around the frame threads and lies along the inner surface of the stent. By contrast, in Davila as shown in Figures 6 and 9B-9C, the graft material is disposed on the inner surface of the stent and the cuffs are folded along the outer surface of the stent. Thus, the graft material that is claimed is positioned and attached to the stent in a manner that is opposite of the graft material disclosed in Davila.

Claims 78 and 84 are further directed to specific embodiments of the stent-grafts disclosed in Applicant's specification. In particular, claim 78 recites the "tubular structure formed of a single frame thread circumferentially wrapped to form a plurality of ring segments connected by a plurality of curved regions, adjacent curved regions extending beyond each other such that the adjacent ring structures are interleaved." This limitation is directed to the embodiment shown in Figures 1-4 of Applicant's specification. (Specification at ¶ [0029]). Claim 84 recites the "tubular structure formed of one or more frame threads connected to a longitudinal support and comprising two opposing fingers, each finger including a distal end extending away from a base connected to the longitudinal support, the fingers being circumferentially wrapped around the longitudinal support." This limitation is directed to the embodiment shown in Figures 5-6 of Applicant's specification. (Specification at ¶ [0040]). The Examiner argues that "Summers discloses several stent patterns in Figures 1-5 and 21 that meet many limitation of the claims." However, the Examiner admits that Summers does not disclose the specific means of attaching the graft to the stent frame. As discussed above, none of the prior art relied upon by the Examiner discloses the claimed structure for attaching the graft to the stent frame. Indeed, the only disclosure that the Examiner

has cited for attaching a graft to a stent frame (Davila) relates to an entirely different stent structure than the structure claimed by Applicant. Applicant respectfully submits that there is no prior art of record that would have enabled one of ordinary skill in the art to attach a partial circumference graft to the stent structures that are claimed in the manner that is claimed.

Claims 75, 79 and 85 recite that the graft material is secured to the support frame by folding the graft material and connecting it around “a single frame thread portion.” Examples of this claimed embodiment are shown in Figures 1 and 5 where the folded end of the graft material is connected around a single frame thread portion instead of around multiple thread portions. This limitation is not disclosed in any of the prior art that the Examiner relies upon. As noted above, the Examiner relies upon Davila for the attachment mechanism of the graft material to the support frame. However, as is clearly shown in Figures 6 and 9B-9C, the graft material in Davila is folded around multiple thread portions, not a single frame thread portion as claimed.

Claims 76, 82, 88 and 90 recite “first and second radiopaque markers” where the first radiopaque marker is “positioned adjacent a first lateral edge of the graft material” and the second radiopaque marker is “positioned adjacent a second lateral edge of the graft material.” This embodiment is shown in Figures 7 and 8A-8B where radiopaque markers 266a and 266b are positioned adjacent the lateral edges of the graft material. As a result of the placement of the radiopaque markers relative to the partial circumference graft material, a physician is able to more easily position the stent-graft in the desired circumferential orientation within the vessel. (Specification at ¶¶ [0045]-[0047]). It is respectfully submitted that this aspect of the invention is not disclosed in the prior art of record.

Claims 77, 83, 89 and 91 recite “a third radiopaque marker” that is positioned “between the first and second radiopaque markers and adjacent the graft material.” This embodiment is shown in Figures 7 and 8A-8B where radiopaque marker 266c is positioned between radiopaque markers 266a and 266b and is positioned adjacent to the graft material. The position of the third radiopaque marker provides an additional visual reference that aids the physician in orienting the stent-graft circumferentially in

the vessel. (Specification at ¶¶ [0045]-[0047]). It is respectfully submitted that this aspect of the invention is not disclosed in the prior art of record.

In view of the arguments above, it is respectfully submitted that the claims as now presented are allowable over the prior art of record. Because the prior art of record does not disclose or suggest all of the limitations of claims 40, 78, 84 and 90, Applicant's independent claims are allowable as now presented. Claims 41-47, 49-50, 73-77, 79-83, 85-89 and 91 are also allowable since these claims depend from claims 40, 78, 84 and 90. Any further arguments that could be made in support of Applicant's dependant claims would be superfluous and are unnecessary at this time.

Conclusion

In response to the Examiner's comments, Applicant has amended claims 40 and 49-50 and has added claims 75-91. Claim 48 has been cancelled. None of the prior art of record discloses or suggests all of the limitations required by the claims as now presented. Thus, Applicant's claims are allowable. Accordingly, Applicant requests reconsideration and allowance of the application.

Respectfully submitted,

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